

(12) **UK Patent Application** (19) **GB** (11) **2 274 650** (13) **A**

(43) Date of A Publication 03.08.1994

(21) Application No 9326077.6

(22) Date of Filing 21.12.1993

(30) Priority Data

(31) 05036062 (32) 01.02.1993 (33) JP

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(51) INT CL⁵

A61L 15/28 15/30 , C09J 105/00 109/00

(52) UK CL (Edition M)

**C3M MXZ M101 M103 M127 M128 M129 M132 M133
M153 M162 M163 M168
U1S S1049**

(56) Documents Cited

**GB 1598968 A GB 1598966 A GB 1088992 A
US 4367732 A**

(58) Field of Search

**UK CL (Edition M) C3M MXAM MXAN MXC MXZ ,
C3U UFB UFZ , C3V VET
INT CL⁵ A61L
ONLINE DATABASES : WPI**

(54) **Composition for skin barrier**

(57) A composition for a skin barrier which is well-balanced in all such properties as preservation stability, flexibility, and durability, which is composed mainly of an adherent rubbery cementing material component (e.g. polyisobutylene or isoprene rubber) and a hydrocolloid component, wherein at least a part or the whole of said hydrocolloid component comprises psyllium seed gum.

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Composition for Skin Barrier

The present invention relates to a composition for a medical skin barrier and, more particularly, a composition for a skin barrier which is used as the material of tapes or the like for fixing medical treating means onto areas of a human body where a relatively large amount of water-containing exudate is exuded, such as for instance an artificial anus, artificial bladder, various fistulas, etc. or for protecting such areas.

In general, by "skin barrier", a covering material having a skin protecting function (the function of maintaining the normal

physiological condition of skin) is meant, but the skin barrier to which the present invention is applied is, particularly, of the type which has such a water-absorbing function as to absorb sweat and exudate fluids to thereby keep the skin at a suitable humidity.

As this type of skin barriers which are relatively popularly commercialized, there are pointed out products for the protection of artificial anuses, artificial bladders, various fistulas and products for protecting or healing wounds and injuries. For instance, in the case of a product for the protection of artificial anuses, artificial bladders and various fistulas, a skin barrier is used for bonding, onto the skin around the excretion opening, a pouch for stocking therein the feces or excrement, urine or other body liquids excreted from said excretion opening. The skin barrier for bonding or attaching such a pouch is used with the aim of ensuring that the bonding or adhesive force thereof is not deteriorated due to the water contained in the excrement and the sweat oozed out from the skin and that the excrements can be infallibly stocked over a long period of time. Or, in the case where a skin barrier is used for protection or healing of a wound or injury, the skin barrier is required to ensure that the skin barrier can perfectly cover the wound, contact the wound closely to a suitable degree, and absorb the excessive exudate fluids to thereby keep the wounded area in a suitably moist state, and help to heal the wound without sticking fast to the wound itself.

As compositions which can constitute such a skin barrier, there can be pointed out those such as a composition which

comprises a hydrophilic polymer alone, a composition which comprises a hydrophilic polymer and a polyhydric alcohol for treating said hydrophilic polymer into a paste or gel, a composition which is formed in such a manner that, to a hydrophilic polymer and a hydrophobic polymer used as base materials, modifiers such as a tackifier, a thickening agent, a moisture maintaining agent, a shape retaining agent, a dispersing agent, etc. are added and rendered into the form of granules, a paste, a gel, or a sheet.

As for the paste composition of the above-mentioned compositions, it is disclosed in Japanese Unexamined Patent Application Publication No. Sho 56-68457 that a small amount of colloidal silica (SiO_2), preferably a fumed silica, is mixed into a skin protection bonding paste comprising a mixture of a hydrocolloid gum and a film forming resin solution, whereby the paste used is sufficiently improved in respect of its durability, stability and shelf life against intestinal fluids or urine. In Japanese Unexamined Patent Application Publication No. Sho 56-89252, it is disclosed that a small amount of colloidal silica (preferably, fumed silica) is mixed into a mixture consisting of hydrocolloid gum and polyhydroxyl alcohol, whereby the resulting paste exhibits a dry adhesion (dry tack) and a wet tack having a high adhesion even if it is contacted with liquid (wet tack) liquid. As for the gel composition, Japanese Unexamined Utility Model Application Publication No. Sho 53-89096 discloses a karaya gum gel product formed in such a manner that a gel composed mainly of karaya gum is embraced by the upper and lower surfaces of a non-woven fabric, a woven fabric, a knitted fabric or other suitable fiber material to thereby enhance the shape retention of said product in its gel

state.

As for skin barriers composed of a hydrophilic polymer and a hydrophobic polymer as main or base materials, the below-stated products are disclosed in Japanese Unexamined Patent Application Publications No. Sho 54-3847, No. Sho 57-169414, and No. Sho 54-4491: An adhesive material for ostomy which comprises a mixture consisting of gua gum, carob gum or a mixture thereof, pectin, karaya gum or a mixture thereof, and a mixture consisting of a pressure-sensitive adhesive component and an bonding force increasing agent or a finely powdered cellulose, dextrin, sodium carboxymethylcellulose or acrylonitrile graft copolymer; a skin barrier composed in such a manner that, to an adherent rubbery cementing agent component and a hydrocolloid as main components, a flow improving agent is added; a medical cementing agent which comprises a mixture consisting of a pressure-sensitive adhesive component, a mineral oil and a hydrocolloid or an adhesive force increasing agent, or a mixture consisting of hydrocolloid and an adhesive force increasing agent.

However, among such conventional skin barriers, there is none which is well balanced in respect of the possession of all the following excellent properties or characteristics: An excellent preservation stability to ensure that the skin barrier can be free from deformation even if it is preserved for a long time, an excellent flexibility to ensure that the skin barrier can get to fit the irregular skin surface, and an excellent durability to ensure that the skin barrier is free from deformation or collapse while in use.

It is the object of the present invention to provide a composition for skin barrier which is well balanced in all the phases of preservation stability, flexibility, and durability.

In order to achieve the above-mentioned object, according to the present invention, a part or the whole of the hydrocolloid component of a composition which is composed mainly of an adherent rubbery cementing material component and a hydrocolloid component is composed of psyllium seed gum.

It is advantageous if at least more than 5 parts and less than 150 parts of psyllium seed gum with reference to 100 parts of the adherent rubbery cementing material component is contained as a part of the hydrocolloid component of said composition.

As the adherent rubbery cementing agent, there is used an elastomer component such as natural rubber, polyisobutylene, polybutadiene, polyisoprene, styrene-isoprene-styrene, polyurethane, polyacrylic ester, polyacrylic alkyl ester, polyvinyl alkyl ether, or polysiloxane, etc. alone or a mixture thereof. Further, it is also possible to add, as required, polyterpene resin, gum rosin, rosin ester, a rosin derivative, oil-soluble phenol resin, cumarone indene resin, or a petroleum hydrocarbon resin as a tackifier and also a mineral oil, a liquid or a low molecular weight elastomer component such as liquid polybutene or liquid polyacrylate as a softener; and it is also possible to further add an antioxidant or the like. Preferable materials for the adherent rubbery cementing agent are polyisobutylene, SIS, polyacrylic alkyl ester, and

polyurethane which are all less stimulative to the skin.

As the hydrocolloid, either a natural or semisynthetic or synthetic material can be used; in this connection, it is pointed out by way of example that there are natural polysaccharide such as karaya gum, guar gum, tragacanth gum, locust bean gum, acacia gum (gum arabic), kisanthan gum, karaginan, psyllium seed gum, starch, sodium alginate, pectin, gelatin, collagen, semisynthetic or synthetic polymers such as EC, HEC, pullulan, dialdehyde starch, PVP, sodium polyacrylate, polyethylene oxide, hydrophilic polymer synthesized from acrylic acid and starch.

Of the hydrocolloid components, the psyllium seed gum which should particularly be added is the natural vegetable gum collected from the seeds of *Plantago ovata* Forskal, etc. belonging to the *Plantago* species (a kind of broad-leaved plantain) cultivated mainly in the Mediterranean region of Europe and India. This psyllium seed gum has long been used as an antifebrile, medical treatment agent pertaining to dysentery, and as a medicament for intestinal sore, dry cough, hoarse or husky voice, burn, skin grazing, etc.; and further, said psyllium seed gum is used as a hair-setting lotion which is an article of cosmetics, as a stabilizer for foodstuffs, as a viscosity increasing/stabilizing agent, etc. As for the properties of the psyllium seed gum, the color of the psyllium seed gum sold in the market is white and its particle size is 20 to 300 mesh.

In the present invention, it is desirable to use 5 to 150 parts and, more preferably 10 to 80 parts - based on 100 parts

of the adherent rubbery cementing agent component - of a psyllium seed gum of 50 to 150 mesh. From the viewpoint of the purpose of the present invention to obtain a skin barrier having a high preservation stability, a sufficient flexibility, such a high shape retention that the skin barrier is not collapsed when it has absorbed water, and a sufficient durability, it is not desirable to use less than 5 parts of psyllium seed gum since, in such a case, the preservation stability of the skin barrier is so poor that, if it is left to stand at a high temperature for a long time, said skin barrier is liable to flow so that it readily gets out of shape, and, when the skin barrier has absorbed water, it is apt to collapse, thus failing to ensure that the skin barrier has a high durability. On the other hand, if more than 150 parts of psyllium seed gum is used, the preservation stability of the skin barrier becomes very high, and its durability against the water absorption thereof also becomes very high, but the flexibility of the skin barrier is spoiled, so that the skin barrier does not well get to fit the skin, and its water absorption is deteriorated; thus, the resulting skin barrier turns out to be unsuitable as such.

The skin barrier according to the present invention is composed in such a manner that fine particles of the psyllium seed gum which is a part of the hydrocolloid component are dispersed in an adherent rubbery cementing material component, so that said fine particles become cores, which are connected together by the adherent rubbery cementing component, whereby the skin barrier retains its shape; thus, the skin barrier is provided with the advantageous characteristic that the phenomenon can be prevented that, when the other hydrocolloid

component absorbs water, the skin barrier would be swollen, the adherent rubbery cementing material component would be thinned, and thus the skin barrier would become apt to get out of shape. In the skin barrier according to the present invention, the flexibility thereof is not lost at normal temperature even if said hydrocolloid component (psyllium seed gum) is added in a large amount, unlike in the case of the conventionally used flow improving agent (silica, zinc oxide, talc, or the like).

Examples of the present invention will now be described together with comparative examples.

First, the following four examples of the present invention were produced:

EXAMPLE 1

100 parts of polyisobutylene having an average molecular weight of 40,000 ("Polyisobutylene 4H" by Nippon Oil Co., Ltd.), 40 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" by Daicel Chemical Industries Co.), 40 parts of psyllium seed gum having a particle size of 60 mesh, and 5 parts of silica ("Aerosil 300" by Japan Aerosil Co.) were fed into a pressure kneader and subjected to a kneading for 5 minutes to obtain a sheet composition for skin barrier.

EXAMPLE 2

100 parts of polyisobutylene having an average molecular weight of 40,000 ("Polyisobutylene 4H" by Nippon Oil Co., Ltd.), 20 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" by Daicel Chemical Industries Co.), 80 parts of psyllium seed gum

of 60 mesh. and 5 parts of silica ("Aerosil 300" by Japan Aerosil Co.) were fed into a pressure kneader and subjected to a kneading for 5 minutes to obtain a sheet composition for skin barrier.

EXAMPLE 3

100 parts of a liquid isoprene rubber having an average molecular weight of 27,000 and a viscosity of 740 poise at 40°C ("Kuraprene LIR-30" by Kuraray Co.), 20 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" by Daicel Chemical Industries Co.), and 40 parts of psyllium seed gum of 60 mesh were fed into a universal mixer and subjected to a mixing for 5 minutes to obtain a paste composition for skin barrier.

EXAMPLE 4

100 parts of a liquid isoprene rubber having an average molecular weight of 29,000 and a viscosity of 740 poise at 40°C ("Kuraprene LIR-30" by Kuraray Co.), 10 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" by Daicel Chemical Industries Co.), and 80 parts of psyllium seed gum of 60 mesh were fed into a universal mixer and subjected to a mixing for 5 minutes to obtain a paste composition for skin barrier.

Next, the following 6 examples - some of which were composed with no content of psyllium seed gum, others were composed with too low a content of psyllium seed gum, and still others were composed with an excessively high content of said psyllium seed gum - were produced as comparative examples:

COMPARATIVE EXAMPLE 1

100 parts of polyisobutylene having an average molecular

weight of 40,000 ("Polyisobutylene 4H" by Nippon Oil Co., Ltd.), 80 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" BY Daicel Chemical Industries Co.), and 5 parts of silica ("Aerosil 300" by Japan Aerosil Co.) were fed into a pressure kneader and subjected to a kneading for 5 minutes to obtain a sheet composition for skin barrier.

COMPARATIVE EXAMPLE 2

100 parts of a liquid isoprene rubber having an average molecular weight of 29,000 and a viscosity of 740 poise at 40°C ("Kuraprene LIR-30" by Kuraray Co.), and 60 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" by Daicel Chemical Industries Co.) were fed into a universal mixer and subjected to mixing for 5 minutes to obtain a past composition for skin barrier.

COMPARATIVE EXAMPLE 3

100 parts of polyisobutylene having an average molecular weight of 40,000 ("Polyisobutylene 4H" by Nippon Oil Co., Ltd.), 56 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" Daicel Chemical Industries Co.), 4 parts of psyllium seed gum of 60 mesh, and 5 parts of silica ("Aerosil 300" by Japan Aerosil Co.) were fed into a pressure kneader and subjected to a kneading for 5 minutes to obtain a sheet composition for skin barrier.

COMPARATIVE EXAMPLE 4

100 parts of a liquid isoprene rubber having an average molecular weight of 29,000 and a viscosity of 740 poise at 40°C ("Kuraprene LIR-30" by Kuraray Co.), 56 parts of sodium carboxymethylcellulose ("CMC DAICEL 1190" by Daicel Chemical

Industries Co.), and 4 parts of psyllium seed gum of 60 mesh were fed into a universal mixer and subjected to a mixing for 5 minutes to obtain a paste composition for skin barrier.

COMPARATIVE EXAMPLE 5

100 parts of polyisobutylene having an average molecular weight of 40,000 ("Polyisobutylene 4H" by Nippon Oil Co., Ltd.), and 160 parts of psyllium seed gum of 60 mesh were fed into a pressure kneader and subjected to a kneading for 5 minutes to obtain a sheet composition for skin barrier.

COMPARATIVE EXAMPLE 6

100 parts of a liquid isoprene rubber having an average molecular weight of 29,000 and a viscosity of 740 poise at 40°C ("Kuraprene LIR-30" by Kuraray Co.), and 160 parts of psyllium seed gum of 60 mesh were fed into a universal mixer and subjected to a mixing for 5 minutes to obtain a paste composition for skin barrier.

Subsequently, the examples of the present invention and the comparative examples mentioned above were examined in respect of the tack, stability, flexibility, durability and water absorption, which are all properties required of a skin barrier. The results obtained are shown in the following table, in which the mark "◎" stands for "very good", the mark "○" stands for "good", and the mark "x" stands for "bad". As is apparent from this table, the examples of the present invention all alike have well-balanced excellent properties, whereas, in the case of the comparative examples, at least a part of said properties is bad in any of them; and thus, they are not adequate as skin barriers.

TABLE 1

	Tack	Stability	Flexibility	Durability	Water Absorption
Example 1	⊙	○	⊙	⊙	○
Example 2	○	⊙	○	⊙	○
Example 3	⊙	○	○	⊙	○
Example 4	⊙	○	○	⊙	○
Comparative Example 1	○	x	⊙	x	○
Comparative Example 2	⊙	x	⊙	x	○
Comparative Example 3	○	x	⊙	x	x
Comparative Example 4	⊙	x	⊙	x	x
Comparative Example 5	x	○	x	○	x
Comparative Example 6	x	⊙	x	x	○

According to the present invention, a suitable amount of psyllium seed gum is added as a component of skin barrier, whereby there is obtained a skin barrier which is well-balanced in respect of all such properties as tack, preservation

stability, flexibility, durability and water absorption which are required of such skin barrier. The present invention thus can provide a composition for skin barrier very useful in medical use.

CLAIMS

1. A composition for a skin barrier which comprises a base component of an adhesive rubbery cementing material and a hydrocolloid component,
5 wherein at least a part or the whole of the hydrocolloid component is composed of psyllium seed gum.
2. A composition for a skin barrier according to claim 1, wherein there is present 5 to 150 parts of
10 psyllium seed gum per 100 parts of the base component.
3. A composition according to claim 2, wherein there is present 10 to 80 parts of psyllium seed gum to 100 parts of the base component.
4. A composition according to claim 1, 2 or 3,
15 wherein the psyllium seed gum has a particle size in the range 50 to 150 mesh.
5. A composition according to any preceding claim, wherein the hydrocolloid component is a natural polysaccharide, a synthetic or semisynthetic polymer or
20 a hydrophilic polymer.
6. A composition according to claim 5, wherein the hydrocolloid component is karaya gum, guar gum, tragacanth gum, locust bean gum, acacia gum (gum arabic), kisanthan gum, karaginan, psyllium seed gum,
25 starch, sodium alginate, pectin, gelatin, collagen, carboxymethyl cellulose (CMC), ethyl cellulose (EC), hydroxyethyl cellulose (HEC), pullulan, dialdehyde starch, polyvinylpyrrolidone (PVP), sodium polyacrylate, polyethylene oxide, and hydrophilic
30 polymer synthesized from acrylic acid and starch.
7. A composition according to any preceding claim, wherein the base component is an elastomeric material.
8. A composition according to claim 7, wherein
35 the base component is natural rubber, polyisobutylene, polybutadiene, polyisoprene, styrene-isoprene-styrene,

polyurethane, polyacrylic ester, polyacrylic alkyl ester, polyvinyl alkyl ether, polysiloxane or mixtures thereof.

9. A composition according to claim 8, wherein a
5 tackifier, a softener or an antioxidant is added to the base component.

10. A composition according to claim 9, wherein the base component in addition includes polyterpene resin, gum rosin, rosin ester, a rosin derivative, an
10 oil-soluble phenol resin, cumarone indene resin, a petroleum hydrocarbon resin, a mineral oil or a liquid or low molecular weight elastomer.

11. A composition substantially as hereinbefore described with reference to and as illustrated in
15 Examples 1, 2, 3, or 4 of the accompanying examples.

Patents Act 1977
Examiner's report to the Comptroller under Section 17
(The Search report)

Application number
GB 9326077.6

Relevant Technical Fields

(i) UK Cl (Ed.M) C3M (MXAN MXAM MXC MXZ); C3V (VET); C3U (UFB UFZ)

(ii) Int Cl (Ed.5) A61L

Search Examiner
K MACDONALD

Date of completion of Search
19 APRIL 1994

Databases (see below)

(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE DATABASES: W.P.I

Documents considered relevant following a search in respect of Claims :-
1-11

Categories of documents

- | | |
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| <p>X: Document indicating lack of novelty or of inventive step.</p> <p>Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.</p> <p>A: Document indicating technological background and/or state of the art.</p> | <p>P: Document published on or after the declared priority date but before the filing date of the present application.</p> <p>E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.</p> <p>&: Member of the same patent family; corresponding document.</p> |
|--|---|

Category	Identity of document and relevant passages		Relevant to claim(s)
X	GB 1598968	(SQUIBB) Claims 1 & 2	at least Claim 1
X	GB 1598966	(SQUIBB) Claims 1 & 2 page 2, lines 42-53	at least Claim 1
X	GB 1088992	(SQUIBB) Claim 1	at least Claim 1
X	US 4367732	(COLOPLAST) Claim 1	at least Claim 1

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